REMARKS

Status of the Claims

Claims 1, 3, 7-12, 15-26, and 33, as previously amended, were pending and under consideration for purposes of the instant Office Action. Claims 2, 4-6, 13-14, and 33 were previously canceled, and claims 27-32 were previously withdrawn from consideration.

Applicants thank the Examiner for the careful consideration of the previous amendments and accompanying remarks. The Examiner's withdrawal of the previous claim objection, in view of applicants' cancellation of duplicate claim 33, is gratefully acknowledged.

In order to provide further clarity, applicants have replaced the pending claims with new claims 34-51 corresponding to claims 1, 3, 7-12, and 17-26, respectively. Claims 15 and 16, and the subject matter recited in those claims, are no longer being pursued in the new claims.

Amended claim 1, now presented as new claim 34, is believed to more particularly recite the configuration of the claimed tablet according to the subject invention, and now refer to a tamping step used in making the claimed invention. For example, a tamping step is now included in the claims to distinguish the subject invention from the cited Hess reference. Additional amendments are incorporated into new claim 34 and are discussed in more detail, below, pointing out the specific support for each recitation in the claim.

Claim 10 (now claim 39) is also presented in amended form to address the rejection under 35 USC 112. New claim 39 (formerly claim 10) corrects the recitation of the "first" segment and clarifies that the segment derived from a granulation that does not contain a drug is the "top inactive" segment. Similar corrections are incorporated into claims 35-38.

Applicants respectfully submit that the amendments are supported by the specification and that no new matter has been added.

New rejections under 35 USC 112, 35 USC 102(b) and 35 USC 103(a) are presented in the instant Office Action. These rejections are discussed below in view of the newly presented (and amended) claims.

Rejection under 35 USC 112

Claim 10 (now claim 39) was rejected as indefinite in view of the recitation of a "first" segment derived from a granulation that does not contain a drug. Applicants intended to direct claim 10 to further define the top inactive segment as being derived from a granulation that does not contain a drug. Clam 39, as presented, is believed to correct the reference to the "first" segment, and now refers to a "top inactive" segment. Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 USC 102(b)

Claims 1, 3, 7-9, 11-12, and , 15-17 (now claims 34-38, 40-41, and 44 – claims 15 and 16 no longer being pursued) remain rejected as being anticipated under 35 USC 102(b) over Hess (CH648754), an English translation of which was provided by the applicant. This rejection is respectfully traversed.

Applicants believe that a clear understanding of the limitations recited in new claim 34 may clarify the distinctions from Hess.

Claim 34 provides:

Claim 34	Distinction from Hess
A compressed, layered pharmaceutical tablet formed in a tablet die having an embossed bottom tablet punch and a top tablet punch[1], said tablet comprising [1]*Support is provided in the specification at page 6, lines 6-10 of the specification*	Hess does not provide an embossed bottom tablet punch and a top tablet punch that is not embossed. The subject tablet is formed by a tablet die having a top punch that is not embossed because it forms a flat top surface in all layers (see further claim language in claim 1). This distinction for a tablet according to Hess is clear from the description and drawings in Hess which describe and show a tablet scored in the top layer only, or a tablet having a score in both the top and bottom layer. Hess does not describe or show a tablet that is scored in the bottom layer only from an embossed bottom punch and having a top layer that is not scored as in the claimed invention.

one or more layers of a powder or granulation[2] composition containing an effective amount of one or more active drugs, wherein said active drug-containing composition is filled into the tablet die wherein the embossed bottom tablet punch forms a divided active bottom layer or layers[3], said layer or layers being tamped using the top tablet punch to provide first and second unitary segments each having a level top surface following said tamping[4]; and [2]*Powders and granulations are supported in the specification, beginning at page 6, et seq., including the Description of the Preferred Embodiments, at page 36, et seq.* [3]*This aspect is supported in the specification at pages 6-7 and at page 12, et seq.* [4]*Tamping is supported at pages 6 and 12-13 of the specification and the level top surface of the bottom layer (and first and second unitary segments formed thereby) is supported by the drawings, particularly Figs 4a and 4b.*	Hess does not describe an active layer as the first layer that is tamped to form a level top surface. Hess describes and shows a tablet that, in each instance, has a score formed in the top surface of the tablet. This configuration requires an embossed top punch which cannot be used to tamp any layer without forming an indentation or score in that layer. Formation of an indentation or score in the first layer results in an uneven (non-level) top surface of the first layer.
one or more layers of a second powder or granulation composition containing either an undetectable amount of drug or a pharmacologically ineffective amount of drug, wherein said second composition is filled onto the level top surface of said first and second unitary segments in the tablet die, said second composition forming an undivided, non-unitary inactive segment[5] having a bottom and top surface, wherein only the bottom surface contacts said level top surfaces of said first and second unitary active segments, [5]*Support is provided in the specification, e.g., page 6*	Hess does not describe a tablet having an inactive top layer (formed onto an active bottom layer). Hess only describes a tablet having an inactive bottom layer when the top layer is active ("S2" [bottom layer] can be placebo). Further, Hess describes and shows a scored top layer. This can only result from an embossed top tablet punch. When the top tablet punch is embossed, a level top surface of the bottom layer cannot be provided. In accordance with Hess, either the bottom layer is not tamped (which results in a mounded bottom layer from the fill), or the bottom layer is tamped, which will result in an indentation in the top surface of the bottom layer – not a level top surface of the bottom layer as claimed.

wherein the active unitary segments and inactive non-unitary segment are compressed to form a whole tablet, said tablet being divisible by breaking through the inactive non-unitary segment, without breaking of the first and second unitary segments,[6] [6]*Support is provided at page 17 of the specification.*	Hess describes dissolution rates that differ in whole tablets versus halved tablets, indicating that breakage occurs in the active portion of the halved tablet, thereby affecting the dissolution. Thus, Hess does not provide a tablet which is "divisible by breaking through the inactive non-unitary segment, *without* breaking of the first and second unitary segments" as claimed.
wherein the terms "bottom" and "top" refer to the orientation of the tablet in the tablet die during compression.[7] [7]*Support is provided at page 11, lines 30-33, along with page 18, lines 9-17 describing the spatial orientation of the tablet, including the "top" and bottom" as positioned "in the tablet die."*	The significance of the direction and orientation of the tablet "in the tablet die" means that the tablet is formed in a particular order – active bottom layer, which is scored by an embossed bottom tablet punch forming a divided layer and unitary segments, tamping by a top tablet punch to form a level top surface in the bottom layer to interface with the top, inactive layer which is undivided (no embossing in the top punch). Making a tablet of Hess, in the opposite order as described in Hess, and then rotating that tablet 180° does NOT form the claimed tablet. The embossed top punch used in Hess, if a tamping step is employed, forms a disadvantageous groove in the top surface of the bottom layer.

From the above table, it can be seen that the subject invention is directed to a tablet having a bottom layer containing an active drug, wherein the bottom active layer is scored, and a top layer forming an inactive segment. The top inactive segment is not scored because it is formed by a top punch that provides a level top surface in the bottom layer (segments). By contrast, Hess teaches a layered tablet having, in each instance, a score in the top layer of the tablet. Thus, a top punch that forms a score cannot also form a level top surface in the bottom layer(s). Because Hess does not teach a tablet having a bottom active layer which is scored, and a top inactive layer which is not scored, the cited reference cannot anticipate the claimed invention.

The Examiner suggests that the claim's reference to a "top" layer and a "bottom" layer is relative to the orientation of the viewer of the tablet and that simply rotating the tablet of Hess 180° would result in a tablet as claimed. Although such rotation may, at first blush, appear to result in the claimed tablets, this is simply not the case. The subject invention is specifically described as to its orientation in the tablet die.

As explained in Dr. Beach's Expert Declaration (the Beach Declaration, copy attached) submitted with the previous Reply, applicants discovered that a divided layer forming first and second unitary active segments, as claimed, requires the score to be formed in the bottom active layer using an embossed bottom punch. Reasons for this requirement include:

(1) only an embossed bottom punch can provide adequate separation of the layer into discrete unitary segments, and

(2) only an embossed bottom punch (and an unembossed top punch) allows for tamping of the first, bottom layer to form a level or planar top surface of that layer so that the interface of the first and second layers is uniform.

By contrast, an embossed top punch, as in Hess, precludes tamping because the tamping step, using an embossed top punch, will necessarily form an undesired indentation in the top face of the bottom layer. That indentation is filled in by the second layer, resulting in incomplete separation of the scored active layer and a "bulged" interface between the active and inactive layers. These distinctions are clearly illustrated in the Figures attached to the Beach Declaration. Specifically, Fig. 1 shows the "bulged" top and bottom layers created by tamping with an embossed top punch, and Fig. 2 shows the more completely divided bottom layer and resultant unitary segments by use of an embossed bottom punch – with uniform and level surfaces interfacing the layers, and no "bulging" of one layer into another.

Significantly, rotating 180° the tablet shown in Fig. 1 (generally prepared as described in Hess) does NOT result in the tablet of the subject invention, which is shown in Fig. 2. Thus, claimed tablet is different from, and not anticipated by, Hess. All of the claims in the subject application incorporate this "scored bottom layer" distinction and therefore are not anticipated by Hess. Reconsideration and withdrawal of the anticipation rejection under 35 USC 102(b) is respectfully requested.

Rejections under 35 USC 103(a)

Claims 10, 16, and 21-26 (now claims 39 and 46-51 – claim 16 no longer being pursued) stand rejected as being unpatentable under 35 USC 103(a), citing Hess (CH648754), in view of Schmidt (US 4,786,507). Applicants respectfully traverse.

The Office Action indicates that Hess suggests a placebo layer, but does not expressly disclose a granulation that does not contain a drug. The secondary reference of Schmidt is then used to support a disclosure of an inactive granulation (not containing a drug). Schmidt describes formation of a tablet having a bottom inactive layer and a top active layer, or the reverse (see col. 3, lines 60-64). However, Schmidt does not describe or show a scored active layer and does not recognize the problem addressed by the subject invention.

Further, Schmidt cannot be understood as providing any teaching that would cure the defect of Hess, which is described above in distinguishing Hess from the subject invention regarding the anticipation rejection. Both cited references fail to describe a bottom-scored active layer forming unitary active segments. Therefore, irrespective of whether Hess or Schmidt teaches a placebo layer, neither reference taken separately or combined, teaches or suggests a tablet having a bottom active layer, which is scored to form unitary active segments from that bottom layer, and a top inactive layer as claimed.

Applicants' discovery that the *bottom* active layer must be scored (i.e., using an embossed bottom punch) in a tablet as claimed for the subject invention provides certain unexpected advantages that are not exhibited by tablets as described in either of the cited references of Hess or Schmidt. A fully functional tablet of the subject invention is formed having a bottom layer which is preferably tamped prior to disposition of the top inactive layer. However, providing an embossed top punch, as taught by Hess, precludes tamping because the tamping step, using an embossed top punch, will necessarily form an undesired indentation in the top face of the bottom layer. Nowhere is this deficiency of Hess cured by the description in Schmidt.

The disadvantage created by forming a tablet according to Hess (and/or Schmidt) is an indentation in the top surface of the bottom layer formed by an embossed top punch. This indentation is then filled in when the second, inactive granulation (the top layer) is disposed onto that first layer, resulting in an uneven or un-level surface of and interface between the layers. The resulting uneven interface prevents separation of the bottom active layer into discrete active (unitary) segments that are breakable through the score with minimal, if any, exposed surface area of the active, leading to equivalent release profiles of each segment following tablet division.

The Beach Declaration points out that the Hess reference, itself, presents data showing the failure of the Hess tablets to maintain equivalent release profiles when broken, as compared to the release profiles exhibited by the whole tablets. Schmidt provides no teaching or suggestion regarding a cure to this deficiency of Hess. The Schmidt patent, at col. 3, lines 11-24, mentions only the desire to maintain the tablet's capability to be divided, as in conventional tablets. Schmidt does not mention dividing the tablet through a score, nor does Schmidt describe the formation of unitary segments in the active layer to facilitate such division, as is expressly claimed for the subject invention.

Based on the differences between the subject invention and Hess and/or Schmidt, applicants respectfully submit that neither of the cited references provides a teaching or suggestion of the subject invention as distinctly claimed. Nor is there any suggestion in Hess or Schmidt to modify the teachings to arrive at the subject invention. Accordingly, Hess, taken alone, or in combination with Schmidt clearly fail in providing a reasonable expectation of successfully arriving at the subject tablets. Neither Hess nor Schmidt would lead a person of ordinary skill in the art to the tablets as claimed, and having the divisibility advantages as described. Therefore, Hess and/or Schmidt would not have made obvious the subject invention.

Reconsideration and withdrawal of the obviousness rejection citing Hess in combination with Schmidt, is respectfully requested.

Claim 18 (now claim 43) is rejected under 35 USC 103(b) as being unpatentable over Hess (CH648754) in view of Schmidt (US 4,786,507), and further in view of Nesselroad, III (US 2004/0167207). The deficiencies of the teaching of Hess and the failure of Schmidt to cure those deficiencies are discussed above and incorporated by reference for purposes of this further rejection. The reference of Nesselroad further fails to cure the deficiencies of Hess and Schmidt taken alone or together.

Nesselroad is cited for its disclosure of using warfarin as an active pharmaceutical ingredient, or drug, in a tablet – an element not expressly disclosed in Hess of Schmidt.

However, there is no teaching or suggestion in Nesselroad of a warfarin-containing tablet comprising a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored. Thus, the deficiencies of Hess and Schmidt are not cured by Nesselroad and the combination of these references fails to make obvious the claimed invention.

Withdrawal of this obviousness rejection citing Hess in combination with Schmidt and/or Nesselroad, is also respectfully requested upon reconsideration.

Claim 19 (now claim 44) is rejected under 35 USC 103(b) as being unpatentable over Hess (CH648754) in view of Schmidt (US 4,786,507), and further in view of Eberlin et al. (US 3,696,091). The deficiencies of the teaching of Hess and the failure of Schmidt to cure those deficiencies are discussed above and incorporated by reference for purposes of this further rejection. The reference of Eberlin further fails to cure the deficiencies of Hess and Schmidt taken alone or together.

Eberlin is cited for its disclosure of using digoxin as an active pharmaceutical ingredient, or drug, in a tablet – an element not expressly disclosed in Hess of Schmidt. However, there is no teaching or suggestion in Eberlin of a digoxin-containing tablet comprising a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored. Thus, the deficiencies of Hess and Schmidt are not cured by Eberlin and the combination of these references fails to make obvious the claimed invention.

Withdrawal of this obviousness rejection citing Hess in combination with Schmidt and/or Eberlin, is also respectfully requested upon reconsideration.

Claim 45 is rejected under 35 USC 103(b) as being unpatentable over Hess (CH648754) in view of Schmidt (US 4,786,507), and further in view of Franz, et al. (US 6,555,581). The deficiencies of the teaching of Hess and the failure of Schmidt to cure those deficiencies are discussed above and incorporated by reference for purposes of this further rejection. The reference of Franz further fails to cure the deficiencies of Hess and Schmidt taken alone or together.

Franz is cited for its disclosure of using levothyroxin as an active pharmaceutical ingredient, or drug, in a tablet – an element not expressly disclosed in Hess of Schmidt. However, there is no teaching or suggestion in Franz of a levothyroxin-containing tablet comprising a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored. Thus, the deficiencies of Hess and Schmidt are not cured by Franz and the combination of these references fails to make obvious the claimed invention.

Withdrawal of this obviousness rejection citing Hess in combination with Schmidt and/or Franz, is also respectfully requested upon reconsideration.

Applicants believe the subject claims, as now presented, are in condition for allowance, and respectfully request that a Notice of Allowance be issued for the instant application.

Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

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